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July 16, 2002

Daniel E. Troy, Esquire (GCF-1)  
General Counsel  
Food and Drug Administration  
Room 6-05  
5600 Fishers Lane  
Rockville, Maryland 20857

Dear Dan:

Thank you again for meeting with us on July 10 to discuss the petition for reconsideration. Tom and I felt that it was a very constructive discussion. We promised to get back to you on one particular matter relating to the need for documentation of compliance with foreign law.

First, as we discussed, there can be no objection from a policy standpoint to a general requirement that every company must have adequate documentation in its files to support its conclusion that the product does not violate the laws of the foreign country to which it is exported. This would allow each company to keep those records in whatever form best suits its established business practices. Such a requirement would be unobjectionable, because any responsible company must have some form of assurance that it meets foreign law before it could ship the product. By eliminating the need for an affidavit by a high-ranking company official, it would substantially reduce the regulatory burden but would still require compliance with Section 801(e)(1).

Second, we discussed the possibility of continuing the requirement of an affidavit in the unique and limited situation where FDA has established a specific requirement for a food or cosmetic in order to prevent a serious health hazard and the product to be exported does not meet that requirement. This would arise in two instances. The first instance would be where FDA has established a label warning for a product. An example would be the warning for aspartame in 21 C.F.R. 172.804. The second instance would be where FDA has established a specific limit on the presence of an ingredient or substance because of substantial safety concerns. Examples would be Compliance Policy Guides 555.300 for salmonella and 555.400 for aflatoxin in food and the limit on mercury in cosmetics in 21 C.F.R. 700.13. This would not, however, include the limits customarily established in food additive, GRAS, and color additive regulations because these are set simply at the level requested by the manufacturer and not because of a specific determination by FDA that any higher limit is a serious health hazard. It

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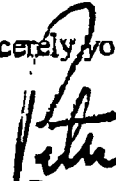
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would also not apply to a food ingredient or a color ingredient which FDA has not reviewed and therefore has taken no action. It is common industry practice to manufacture products in the United States that contain ingredients or levels of ingredients approved or permitted by foreign countries but not by FDA. If affidavits were required for all of these types of situations, it would simply drive food and cosmetic manufacturers abroad. As we discussed at the meeting, we do not believe that is the intent of the new Administration to impose new regulatory requirements that force American business to relocate offshore after 64 years of doing the same thing in this country.

Finally, as you know, we strongly believe that, even if FDA has the legal authority to establish documentation requirements relating to exports, it has no legal authority to require those records to be inspected by the agency. These are entirely separate issues.

Sincerely yours,



Peter Barton Hutt  
Counsel for CTFA and GMA